Remarks:

The above amendments and these remarks are responsive to the non-final Office action dated August 11, 2006, and are being filed under 37 C.F.R. § 1.111. Claims 55-100, 102-120, 123-128, 131-136, 140, 141 and 145-151 are pending in the application, with claims 55-82, 134, 135, 145-147 and 151 being withdrawn from consideration. In the Office action, the Examiner (1) rejected claim 83 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, and (2) rejected all of the pending, non-withdrawn claims under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,860,957 to Jacobsen et al. ("Jacobsen") combined with one or more other references. Applicant traverses the rejections, contending that all of the pending claims are patentable over the cited references.

Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention, applicant has amended claims 83 and 98-100, and has canceled every withdrawn claim (claims 55-82, 134, 135, 145-147 and 151) without prejudice. However, applicant reserves the right to pursue the subject matter of the canceled claims and previously presented claim 83 at a later time. Furthermore, applicant has presented remarks showing that claim 83 meets the written description requirement of Section 112 and that all of the pending claims are patentable over the cited references. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and prompt allowance of all of the pending claims.

PAGE 13/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

I. *Amendments to the Claims*

The present communication amends claims 83 and 98-100 (and cancels every withdrawn claim). The following section (Section II) addresses amendment of claim 83. Claims 98-100 were amended to address typographical errors, namely, omission of a preposition ("with") from claim 98 and omission of the word "portion" from the term "container portion" in claims 99 and 100.

II. *Rejection under 35 U.S.C. § 112*

The Examiner rejected claim 83 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner asserted that "there is no support in the disclosure as originally filed for a droplet volume of less than or equal to 100 picoliters." In addition, the Examiner stated that "references to prior art droplet volumes do not constitute support for the added limitation regarding droplet volume." Applicant traverses the rejection, contending that the present application, as filed, clearly conveys the recited droplet volume. For example, paragraph [36] states "for instance, some of the more recent inkjet print cartridges are able to deliver droplets of a size on the order of 0.5-6 picoliters, although larger droplets can also be generated, for example droplets of 10, 50, 100 or more picoliters." The very next paragraph states that "these inkjet printheads [described in the preceding paragraphs] may be used in the cutaneous application systems illustrated here." Therefore, the present application clearly indicates that the droplet volumes listed for inkjet print cartridges may be used for cutaneous application systems, and thus the droplet volume recited by claim 83 is supported.

PAGE 14/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

Nevertheless, for the reasons set forth above, applicant has amended claim 83 such that the recitation of each droplet being "less than or equal to 100 picoliters" has been deleted from the claim. Accordingly, the rejection under Section 112 should be moot and thus should be removed.

III. Rejections under 35 U.S.C. § 103

The Examiner rejected all of the pending (non-withdrawn) claims under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen in view of one or more additional references. Claims 83-100, 108, 109, 119-123, 126-130, 140, 141 and 148-150 were rejected over Jacobsen in combination with U.S. Patent Application Publication No. 2003/0016262 to Crivelli ("Crivelli"). In addition, claims 102-107 were rejected over a combination of Jacobsen, Crivelli, and U.S. Patent No. 6,325,475 to Hayes et al. ("Hayes"); claims 124, 125, 132, and 133 were rejected over a combination of Jacobsen, Crivelli, and U.S. Patent No. 5,179,947 to Meyerson et al.; and claim 136 was rejected over a combination of Jacobsen, Crivelli, and U.S. Patent No. 6,564,092 to Nakamura et al. Applicant traverses the rejections; each of the pending claims is patentable over the cited references at least for the reasons set forth below.

PAGE 15/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

A. *Claims 83-90, 102-104, 108, 118-120, 123-125, 136, 140, 148 and 149*

Independent claim 83 is directed to a method, as follows:

> 83. (Currently Amended) A method of administering a bioactive composition to a subject, the method comprising:
>
> applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;
>
> dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface~~, wherein each bioactive composition droplet is less than or equal to 100 picoliters~~; and
>
> retaining the bioactive composition in prolonged contact with the cutaneous surface.

In the Office action, the Examiner rejected claim 83 over a combination of Jacobsen and Crivelli. However, applicant submits that the Examiner has not established a *prima facie* case of obviousness. In particular, applicant submits that (1) the cited references, alone or in combination, do not teach or suggest every element of claim 83, and (2) there is no teaching, suggestion, or motivation to combine the references.

Jacobsen relates to a multi-pathway electronically-controlled drug delivery system that is strapped to a patient's limb or torso. The system is disclosed to administer a drug via ignition of a propellant charge. The ignited propellant charge expands to force a drug from a storage reservoir to a site above or below the skin. In various embodiments, the system administers the drug by (1) transdermal delivery (passive or iontophoretic) via a pad (e.g., see Figures 5 and 6), (2) needle-less injection through the skin via a piercing jet of fluid (e.g., see Figure 7), or (3) needle-based injection through the skin (e.g., see Figure 8).

PAGE 16/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

Significantly, neither needle-less nor needle-based injection through the skin involves "retaining the bioactive composition in prolonged contact with the cutaneous surface," as recited by claim 83.

The Examiner referred to the device of Figure 8 of Jacobsen in rejecting claim 83. A portion of Figure 8a is reproduced below to facilitate review. Figure 8a relates to a delivery device for injection of a drug through the skin with a needle. Ignition of a propellant charge 526 urges drug pod 510 downward such that a hypodermic needle 502 pierces a seal 540 and then the skin of a patient (col. 12, lines 40-42). Pressure from the propellant charge then collapses a drug-containment pouch 506 and forces the drug "through the hypodermic needle into the tissue of the patient." Accordingly, operation of the device of Figure 8a involves neither "dispensing the bioactive composition in droplets" toward the cutaneous surface nor "retaining the bioactive composition in prolonged contact with the cutaneous surface," as recited by claim 83. More particularly, the device of Figure 8a dispenses a stream of a drug below the skin, instead of in contact with the cutaneous surface of the patient.

PAGE 17/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

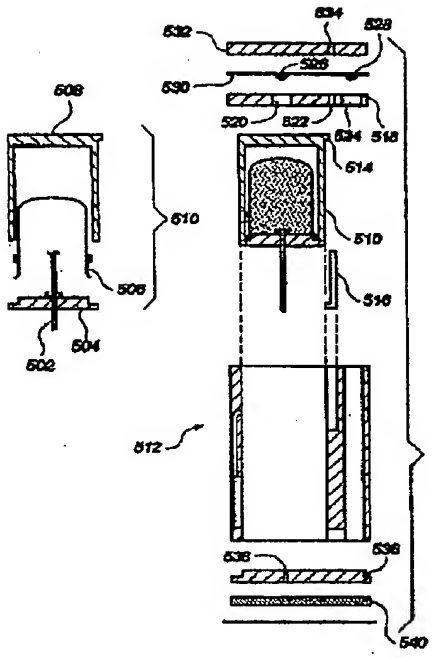

Fig. 5A

Figure 5 of Jacobsen relates to transdermal delivery via a pad. Figure 5 is reproduced below to facilitate review. The device of Figure 5 has a pod housing 250 divided into an upper chamber 290 and a lower chamber 300 by a piston 320. Ignition of a propellant charge 280 located in the upper chamber forces the piston toward an aperture 350 formed in the pod housing and providing an outlet for drug disposed in lower chamber 300. Pressure exerted on the drug in the lower chamber breaks a foil barrier 360 covering aperture 350 such that "the drug flows out of the chamber 300 and, in this particular drug delivery system, fills a pad 370 directly beneath the pod aperture 350" (col. 10, lines 31-33; emphasis added). Furthermore, Jacobsen discloses that "the drug is constrained by the surrounding pad 370, and is absorbed through the patient's skin" (col. 10, lines 33-35).

PAGE 18/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

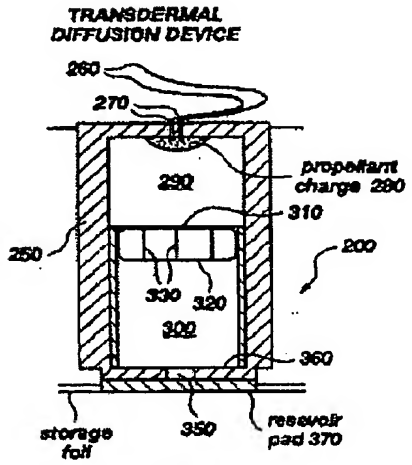

Fig. 5

However, Jacobsen does not teach or suggest dispensing the drug in drops of any size, and thus particularly does not teach or suggest "dispensing the bioactive composition in droplets," as recited by claim 83. In particular, the device of Jacobsen blocks drop formation because Jacobsen discloses placement of pad 370 in abutment with aperture 350 such that drops cannot form as they leave the aperture.

Crivelli relates to a fluid-ejection device, namely, a printhead for a thermal inkjet printer, and a method of operating the printhead. The printhead has a plurality of firing resistors (heating elements) operatively coupled to a corresponding set of orifices defined by an orifice plate. The firing resistors are energized selectively adjacent corresponding orifices such that ink is fired in droplets from the orifices. The droplets are disclosed to have a volume of 20 picoliters in an exemplary embodiment. Crivelli discloses no other use for the fluid-ejection device other than printing with ink, and thus does not disclose, teach, or suggest the printhead (or any other fluid-ejection device)

PAGE 19/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

dispensing a bioactive composition in droplets toward a cutaneous surface or retaining the bioactive composition in prolonged contact with the cutaneous surface.

It is submitted that the combination of Jacobsen and Crivelli does not produce the claimed invention. In particular, Jacobsen discloses disposing a drug-receiving pad in abutment with an aperture of a drug delivery device (e.g., see Figure 5 above), for cutaneous delivery of the drug. (Crivelli does not teach or suggest any type of cutaneous delivery.) Accordingly, the combination of Jacobsen and Crivelli would place the drug-receiving pad of Jacobsen in abutment with the orifice plate of the printhead of Crivelli. In this configuration, the pad would block droplet formation by the printhead and would tend to draw ink from the printhead by capillary action, thereby rendering the printhead non-functional for dispensing droplets. Furthermore, it would not have been obvious to space the pad from the printhead of Crivelli because this would have been expected to permit evaporation of fluid from the pad, thereby drying out the pad and preventing the drug from diffusing through the skin.

Even if the combination of Jacobsen and Crivelli would have produced the claimed invention, and applicant contends that it would not, it is submitted that there is no teaching, suggestion, or motivation to combine these references. As described above, Jacobsen relates to delivery of a jet of fluid (a drug) as an uninterrupted stream, not in drops, based on a single firing event. In contrast, Crivelli relates to thermal inkjet printing, which involves patterned delivery of a large number of droplets to print media, for rapid evaporation, based on a corresponding large number of firing events. Accordingly, Jacobsen and Crivelli relate to completely different approaches to, and

PAGE 20/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

reasons for, delivering fluid. Furthermore, at the time of the invention, a method resulting from combination of these references would have been considered by the ordinarily skilled artisan to be inefficient and complicated for drug delivery. For example, Jacobsen discloses an exemplary drug volume of 0.5 mL (500,000,000 picoliters) to be delivered as a single dose by a transdermal drug delivery system (col. 10, lines 48-50), in response to a single actuation event. Crivelli's printhead, based on a disclosed volume per droplet of 20 picoliters, would require 25 million droplets and thus 25 million actuation events to deliver 0.5 mL of drug. Accordingly, applicant submits that there is no teaching, suggestion, or motivation to modify a drug delivery system (Jacobsen) that delivers a drug dose as a single, non-patterned fluid stream, in response to a single actuation event, with a printhead (Crivelli), which would deliver a corresponding volume of ink as millions of droplets in response to millions of actuation events.

In summary, applicant submits that independent claim 83 is patentable over the cited references. Claim 83 thus should be allowed. Claims 84-90, 102-104, 108, 118-120, 123-125, 136, 140 148, and 149, which depend ultimately from claim 83, also should be allowed for at least the same reasons as claim 83.

B. *Claims 91-100, 105-107, 109, 126-128, 131-133, 141 and 150*

Independent claim 91 is directed to a method, as follows:

> 91. (Previously Presented) A method of administering a bioactive composition to a subject, the method comprising:
>
> applying a cutaneous patch to skin of the subject; and
>
> dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice to the patch.

PAGE 21/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

In the Office action, the Examiner rejected claim 91 over a combination of Jacobsen and Crivelli. However, as described above in relation to claim 83, it would not have been obvious to combine Jacobsen with Crivelli because this combination disrupts dispensing of droplets from an inkjet dispenser and because there is no teaching, suggestion, or motivation to combine Jacobsen with Crivelli. For at least these reasons, claim 91 should be allowed. Claims 92-100, 105-107, 109, 126-128, 131-133, 141 and 150, which depend ultimately from claim 91, also should be allowed for at least the same reasons as claim 91.

C. *Claims 102-107*

Claims 102-107 were rejected over a combination of Jacobsen, Crivelli, and Hayes. Each of these claims is patentable at least for the same reasons as claim 83 and claim 91, as described above. In addition, each of these claims is patentable because it would not have been obvious to combine Crivelli and Hayes. Crivelli relates to a fluid-ejection device and method that is intended to reduce aerosol generation (paragraph [0005]). In contrast, Hayes relates to a device for presenting airborne materials to the nose, that is, a device for creating aerosols (for inhalation or sniffing). Accordingly, it would not have been obvious to combine Crivelli and Hayes because these references have contradictory goals. Claims 102-107 thus also should be allowed for at least this additional reason.

PAGE 22/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26

IV. Conclusion

Applicant submits that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicant respectfully requests that the Examiner issue a Notice of Allowability covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner Melanie Jo Hand, Group Art Unit 3761, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on November 13, 2006.

Christie A. Doolittle

PAGE 23/23 * RCVD AT 11/13/2006 8:58:28 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/26 * DNIS:2738300 * CSID: * DURATION (mm-ss):07-26